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09/759,037	01/10/2001	David A. Mark	112701-138	3136

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EXAMINER
SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/759,037	Applicant(s) MARK ET AL.	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-22 are pending in this application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent 5,661,123 ('123), claims 1-22 of US Patent 6,200,950 ('950), claims 1-20 of US Patent 5,549,905 (' 905).

Although the conflicting claims are not identical and introduce different use and various different concentrations of the ingredients, but they are not patentably distinct from the patented claims, because they fail to add a distinctive limitation to those of the patented. For example, claims of the US '123 solely differ from those of the instant application in the amount of energy provided by the protein source. Nevertheless,it would have been obvious to one of ordinary skill in the art at the time of invention to modify such amounts by routine experimentation to optimize the clinical effects.

Similarly, the scope of the claims of the US '950 clearly overlap with those of the instant claims, thus, rendering the instant claims an obvious variant of those patented. Finally, the scope of the claims 1-6 of US '905 also overlap with those of the instant claims in that they appear to encompass a broader genus of compositions. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the amount of hydrolyzed protein source in compositions US '905 by routine experimentation.

2. Claims 1-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 09/622629. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the copending claims clearly overlaps with those of the instant claims, thus, rendering the instant claims an obvious variant of those of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-12, 14-20, 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidl et al US Patent 5,504,072.

The instant claims are drawn to an enteral composition comprising a protein source providing about 15%-20% of the energy of the composition, a carbohydrate source, a lipid source including a mixture of medium and long chain density triglycerides, a Zinc source, a Vitamin C source, a Selenium source, a Taurine source, and a L-Carnitine source, wherein the composition provides a ratio of non-protein calories per gram nitrogen of at least 90:1 and has an energy density of 1.4 kcal/ml. Further the instant claims encompass methods of providing said composition to a patient comprising administration of therapeutically effective amount to the patient wherein said composition is fed through a tube.

Schmidl et al disclose an enteral nutritional formulation that meets the nutritional needs of critically ill and metabolically stressed patients such as patients suffering from trauma, burn, malnutrition, sepsis, cancer, AIDS or other like conditions (see Col 3, lines 34-42). Schmidl et al also disclose an enteral formulation comprising a protein source that can provide approximately 16-25% of the calorie distribution of the composition that can include protein hydrolysate such as whey hydrolysate or alike

consisting of free amino acids, a carbohydrate source (see Col 4 lines 51-67, col 10, lines 43-47), a lipid source including medium and long chain triglycerides, a Zinc source, a Selenium source, a Taurine source, a Cysteine source, a L-Carnitine source, a Vitamin C source (see Col 4 lines 1-51 and Col 8 table), and wherein said formulation provides a non-protein calorie to grams of nitrogen ratio of ranging from 150:1 to 80:1 (see Col 5 lines 64-68 and Col 6 lines 1-11). Schmidl et al further disclose a method for administering said formulation to a patient via various tube-feeding techniques (see Col 7 lines 60-67). Therefore, the nutritional formula of Schmidl et al meets the limitation set forth in the instant claim.

4. Claims 1-12, 14-20, 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Henningfield et al US Patent 5,221,668

Henningfield et al disclose liquid nutritional products for trauma and surgery patient has a caloric density of about 1.2 to 1.5 Kcal/ml, and a calorie nitrogen ratio of about 112:1 to 145:1, wherein the portion of protein system containing whey partially hydrolyzed protein such lactoalbumin, and wherein 18-24% of the calories are provided by proteins, 20-30% are provided by lipids and 50-58% are provided by carbohydrates (see abstract table 1, col 6 lines 25-40, col 9 lines 1-68, col 11, lines 31-42, claims 1, 4, 19 and 22.) The product of Henningfield et al also provide sufficient amount of vitamins in 1,500 Kcal (see col 13 lines 40-46, claims 21-22.) Thus, Henningfield meet the limitations set forth in the instant claims.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-22 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gray et al US Patent 5,714,472.

Gray et al disclose an enteral nutritional formulation that meets the nutritional needs of critically ill and metabolically stressed patients such as post-surgical patients or patients suffering from trauma, burn or related complications (see abstract). Gray's enteral formulation has a caloric density of at least 1.3-1.5 Kcal/ml (see col 3, line 50) and comprise a protein source including protein hydrolysate comprising whey hydrolysate and provides about 22% of the total calories of the formulation, a

carbohydrate source, a lipid source including medium and long chain triglycerides, a Zinc source, a Selenium source, a Taurine source, a Cysteine source, a L-Carnitine source, and a Vitamin C source, wherein said formulation meets the U.S. RDAs recommendations of said nutrients (See col 5 lines 25-38, 65-68, and Col 6 lines 35-42, and Col 7, lines 6-14; Col 9, line 20). Gray et al also disclose a method for providing said formulation to a patient comprising a step of enterally administering to the patient a therapeutically effective amount (see Col 9 and 10, all claims). Therefore, the nutritional formula of Gray meets the limitation set forth in the instant claim.

Applicant is informed that where a composition is claimed in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function or characteristic is not explicitly disclosed by the reference the Examiner can make a rejection under both 35 U.S.C 102 and 103, expressed as 102/103 rejection (see MPEP 2112). In the instant case, the recitation of "a protein source providing about 20% of the energy of the composition" appears to significantly overlap with those ranges taught by Gray. Accordingly, even though Gray's composition provides "about 22%" of the energy of his composition. Examiner views the instant limitation of "about 20%" to be substantially the same as those taught by Gray, because the difference in such percentages encompass a minute variation with respect to the total amount of the protein.

In alternative, where Gray's compositions do not possess or provide the same amount of energy as instantly claimed, absence of showing the criticality, it would have been *prima facie* obvious to optimize the concentrations of Gray's compositions by

routine experimentation (see 2144.05 II). The ordinary skill in the art would have been motivated to optimize the viscosity of the ~~Evans~~ Gray's final formulation, because he would have had a reasonable expectation of success in achieving the desirable clinical outcome modifying Gray's compositions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 13 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidl et al US Patent 5,504,072 in view of Gray et al 5,714,472.

Schmidl et al teach an enteral nutritional formulation that meets the nutritional needs of critically ill and metabolically stressed patients such as patients suffering from trauma, burn, malnutrition, sepsis, cancer, AIDS or other like conditions (see Col 3, lines 34-42). Schmidl et al disclose an enteral formulation comprising a protein source that can provide approximately 16-25% of the calorie distribution of the composition that can include protein hydrolysate such as hey hydrolysate or alike (see Col 4 lines 51-67), a carbohydrate source, a lipid source including medium and long chain triglycerides, a Zinc source, a Selenium source, a Taurine source, a Cysteine source, a L-Carnitine source, a Vitamin C source (see Col 4 lines 1-51 and Col 8 table). Schmidl et al also teach the desired NPC:N ratio for critically ill patients to be in the range of 150:1 to 80:1 (see col 5 lines 65-67 and col 6 lines 1-3). Further it is well known in the

art that the nitrogen content of the composition can be measured to best fit the needs of critically ill patients; as indicated by Schmidl et al (see col 6 lines 2-9). Also the use of antioxidants, vitamins and various minerals is routine in nutrition art, and further Schmidl et al provide such teachings in their patent (see col 9 lines 45-66, col 10 lines 1-25). Schmidl et al further disclose a method for providing said formulation to a patient comprising the step of enterally administering to the patient a therapeutically effective amount (see Col 7 lines60-67). However, Schmidl et al fail to incorporate beta-carotene and L-cystine to their enteral formula.

Gray et al teach the use of Beta Carotene as a precursor of Vitamin A in their compositions (col 6, lines 3-6). The enteral formulation of Gray meets the nutritional needs of critically ill and metabolically stressed patients such as post-surgical patients or patients suffering from trauma, burn or related complications. Gray's formulation has caloric density of at least 1.3 Kcal/ml and comprise a protein source including protein hydrolysate comprising whey hydrolysate, a carbohydrate source, a lipid source including medium and long chain triglycerides, a Zinc source, a Selenium source, a Taurine source, a Cysteine source, a L-Carnitine source, and a Vitamin C source that meets U.S. RDAs recommendations of said nutrients (See col 5 lines 25-38, 65-68, and Col 6 lines 35-42, and Col 7, lines 0-14). Gray et al also disclose a method for providing said formulation to a patient comprising the step of enterally administering to the patient a therapeutically effective amount (Col 9 and 10).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Schmidl's composition to further contain Beta Carotene,

because one skilled artisan have had a reasonable expectation of success to improve Schmidle's composition to meet the vitamin A need of metabolically stressed patients in a critical setting.

7. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trimbo US Patent 5,166,189 in view of Schmidl US Patent 5,504,072, Gray US Patent 5,714,472, and Maubois US Patent 4,427,658 and further in view of Granger et al (JPEN 12:278-281, 1988).

Trimbo et al teach the method of feeding patients with pulmonary disease by administering to a patient an enteral nutritional composition comprising a total calories not less than about 18% protein, about 20-50% carbohydrate, about 40-55% lipids comprising of a mixture of medium and long chain triglycerides, that meets US RDAs recommendations of all vitamins and minerals. Trimbo et al however fails to show the use of hydrolyzed whey protein and their production by using pancreatic enzymes. Trimbo also fails to address the use of said enteral nutritional composition in metabolically stressed patients (see entire patent).

The teachings of Schmidl and Gray are described above. Schmidl fails to use Beta carotene in his compositions and Gray does not explicitly teach compositions providing about 20% of the energy from a protein source.

Maubois et al disclose a method of obtaining hydrolyzed whey protein as well as an enteral nutritional formulation for use in an intensive care setting to the patients who may require a protein intake of the 7-25% of total caloric intake, wherein said protein comprising a hydrolyzed whey protein (see example 5 and 6). Maubois et al fail to

specifically address the U.S. RDA□s nutritional needs of metabolically stressed patients.

It is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. In re Becket, 33 USPQ. 33 (C.C.P.A. 1937). In re Russell 439 F.2nd 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971). Further it is shown in the art that hypermetabolicly stressed patients may suffer from gastrointestinal malabsorption due to the changes of the intestinal mucosa and the intestinal capillary bed; subsequently, said patients experience enhanced protein absorption when a suitable hydrolyzed protein source (such as whey, because of its well balanced aminoacids content) is used (Granger et al, Page 280-281, see discussion).

Therefore, it would have been obvious to one of ordinary skill in the art to modify Trimbo's formulation, as taught by Schmidl, Gray and Maubois and prepare an enteral product that meets the specific nutritional requirements of metabolically stressed patients while providing a suitable hydrolyzed protein source such as whey, because of as taught by Granger, the ordinary skill in the art would have had a reasonable expectation of success in providing elemental protein to a hypermetabolically stressed patient.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, JD can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss
March 23, 2002

MINNA MOEZIE, J.D.
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